

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

JERAD SHORT,

Plaintiff,

v.

CASE NO. 1:14-CV-1025

JANSSEN PHARMACEUTICALS,
INC., AND JOHNSON AND
JOHNSON INC.

HON. ROBERT J. JONKER

Defendants.

OPINION

Plaintiff Jerad Short brought this action against Defendants Janssen Pharmaceuticals, Inc. and Johnson & Johnson, Inc., alleging violations of the federal Racketeer Influenced and Corrupt Organizations Act (“RICO”), *see* 18 U.S.C. § 1962, the Michigan Consumer Protection Act, *see* Mich. Comp. Laws §§ 445.901–.922, and the Michigan Products Liability Act, *see* Mich. Comp. Laws §§ 600.2945–.2949b. Before the Court is Defendants’ Motion to Dismiss for Failure to State a Claim (docket no. 10).

The Court held oral argument on this motion on February 13, 2015. At that time, the Court issued an order regarding supplemental briefing on issues raised during oral argument, including the issue of statutory standing under RICO. Plaintiff Short filed a supplemental brief regarding statutory standing (docket no. 27). Defendants filed a supplemental brief in support of their motion to dismiss for failure to state a claim, also addressing this issue (docket no. 30). Plaintiff Short filed a surreply in response to the Defendant’s motion (docket no. 34).

For the reasons that follow, the Defendants' motion to dismiss is GRANTED.

I. BACKGROUND

This case involves an alleged unlawful marketing scheme. Defendant Janssen Pharmaceuticals is a wholly-owned subsidiary of Defendant Johnson & Johnson, Inc. Defendants' line of business includes the manufacture, labeling, advertisement, and sale of prescription drugs. Defendants allegedly knew that one of its drugs, Risperdal, posed certain health risks to children, including the risk of elevated levels of prolactin, a hormone that can stimulate breast development and milk production, and can result in the gynecomastia disorder in males. (R. 1, Compl. at 6, PageID # 6.) Despite this alleged knowledge, Defendants allegedly instructed its sales representatives to market Risperdal for an off-label use as a safe and effective treatment for various adolescent disorders. (R. 1, Compl. at 7, PageID # 7.) Allegedly included as targets of Defendants' marketing campaign were psychiatric and medical centers located in Michigan. (R. 1, Compl. at 7, PageID # 7.)

Plaintiff Short, a resident of the State of Michigan, was diagnosed with bipolar disorder when he was around ten years old. He received treatment for this disorder at psychiatric and medical centers in Michigan, the same locations where Defendants allegedly had implemented their fraudulent marketing campaign. (R. 1, Compl. at 11, PageID # 11.) Plaintiff's treatment included a prescription for Risperdal. The parties agree that any direct costs for Risperdal were paid by Plaintiff Short's insurance company. The parties also agree that at all times Risperdal was approved for on-label uses by the federal Food & Drug Administration.

Plaintiff contends that as a result of taking Risperdal, he developed the gynecomastia disorder. Plaintiff further contends that he suffered this injury because Defendants failed to provide

complete and accurate information about the risks of taking Risperdal. He filed this action in the U.S. District Court for the Western District of Michigan, on the basis of diversity jurisdiction.

Defendants filed a motion to dismiss, alleging that Plaintiff's claims failed as a matter of law for various reasons. At oral argument, the Court discussed the issue of statutory standing under RICO, inquiring whether Plaintiff himself directly incurred costs as part of a retail purchase of Risperdal. Plaintiff conceded that his insurance company paid the upfront cost for Risperdal, but argued that this fact did not preclude statutory standing under RICO. The Court permitted supplemental briefing on the issue. The matter is now fully briefed and ready for decision.

II. LEGAL STANDARD

The Federal Rules provide that a cause of action may be dismissed for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To survive a Rule 12(b)(6) motion, "a complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). Put differently, if the plaintiffs do "not nudge[] their claims across the line from conceivable to plausible, their complaint must be dismissed." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. In determining whether a claim has facial plausibility, a court must construe the complaint in the light most favorable to the plaintiff, accept the factual allegations as true, and draw all reasonable inferences in favor of the plaintiff. *Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008). Even after accepting all factual allegations as true, for a claim to be valid, the complaint "must contain either direct or inferential allegations respecting all the

material elements to sustain recovery under some viable legal theory.” *League of United Latin Am. Citizens v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007) (internal citations omitted).

The parties agree that Federal Rule of Civil Procedure 9(b), which involves more rigorous pleading standards, applies to Plaintiff’s federal RICO claim. Rule 9(b) states as follows: “In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). “In order to allege fraud with particularity, the plaintiffs, at a minimum, must allege the time, place, and content of the alleged misrepresentation on which [they] relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.” *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 403–04 (6th Cir. 2012) (internal quotation marks omitted).

III. DISCUSSION

A. ‘Federal Law RICO claim’

RICO’s civil-suit provision grants “[a]ny person injured in his business or property by reason of a violation of” RICO’s substantive provisions the right to “sue [] in any appropriate United States district court” and to “recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney’s fee.” *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 612 (6th Cir. 2004) (quoting 18 U.S.C. § 1964(c)). In a relatively recent en banc decision, the Sixth Circuit noted courts’ longstanding concerns about the ever-expanding scope of RICO, observing that it has evolved into something quite different from the original conception of its enactors. *See Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 563 (6th Cir. 2013) (en banc). Accordingly, the Sixth Circuit instructed that “RICO’s breadth is not boundless,” especially with respect to RICO’s requirement that a plaintiff be injured in his business or property, which generally requires an “injury

arising directly out of a retail purchase.” *Id.* at 562, 565 (internal quotation marks omitted). The Sixth Circuit observed that RICO’s injury requirement can “be characterized as a statutory standing issue.” *Id.* at 562 n.2.

“Standing poses a threshold question involving constitutional, prudential and (as in this case) statutory limitations on who may sue, regardless of the merits of that person’s claim.” *See Tyson Foods*, 370 F.3d at 612. The question of statutory standing is “analytically distinct from the question whether a federal court has subject-matter jurisdiction to decide the merits of a case.” *Roberts v. Hamer*, 655 F.3d 578, 580 (6th Cir. 2011). Where a plaintiff lacks statutory standing to sue, the court must dismiss his case for failure to state a claim upon which relief can be granted. *Id.* at 581; *see also Tyson Foods, Inc.*, 370 F.3d at 612 (noting that a plaintiff whose injury is derivative of another’s lacks statutory standing under RICO and “has no right even to file a lawsuit”).

Plaintiff Short’s statutory-standing obstacle in bringing this case is that he did not pay anything for Risperdal. Instead, his insurance company paid the bill, possibly with a co-pay from Short’s mother. Without actually paying anything himself, Short cannot satisfy the RICO statutory prerequisite of “injur[y] in business or property.” *See* 18 U.S.C. § 1964(c). Short’s alleged personal injuries—including any costs necessary to address them—do not satisfy the RICO statutory standing requirement, *see Jackson*, 731 F.3d at 564, as even Short acknowledges. Short must, at a minimum, show some direct, pecuniary injury to his own pocket that is unrelated to the claimed personal injury. His admission that he did not actually expend any personal funds on the Risperdal precludes him from meeting the RICO statutory-standing test.

Plaintiff Short argues that he may, nonetheless, “be said to have incurred the expense,” despite the fact that his insurer paid the liability on his behalf (or because his mother may have

contributed, in the form of co-pays), because an insurance contract is one in which “one party, for consideration, assumes delineated risks of the other party.” *King v. Ford Motor Credit Co.*, 668 N.W.2d 357, 369 (Mich. Ct. App. 2003). Plaintiff Short states that in assessing whether an individual has sustained an injury to his business or property, federal courts generally look to state law to determine whether a particular injury satisfies the definition of property. Plaintiff Short relies heavily on *Shanafelt v. Allstate Insurance Co.*, 552 N.W.2d 671 (Mich. Ct. App. 1996), a Michigan Court of Appeals decision involving the State of Michigan’s No-Fault Automobile Insurance Act, for the proposition that a policyholder still incurs liability for the medical goods or services provided even if an insurance company ultimately covers the cost.

But the argument sidesteps the key statutory term of “injury.” RICO statutory standing requires “injury” to business or property, not merely an acquisition of goods or services for business or property. Even assuming that Plaintiff Short—as a minor—could legally incur contractual liability to pay for his Risperdal prescription, the undisputed fact remains that he never actually had to part with any money for the drugs because his insurance company paid the entire bill for him (possibly with a co-pay from his mother). This is no different than ordering lunch in a restaurant: ordering lunch may obligate you to pay for it, but if your friend picks up the tab, you haven’t suffered any pecuniary injury at all.

Crediting Plaintiff Short’s argument would ignore the limitation that a plaintiff must suffer an “injury to business or property” to file a suit under RICO, which the Sixth Circuit has observed carries “restrictive significance.” *See Jackson*, 731 F.3d at 564. Accordingly, because Plaintiff has not alleged, and cannot allege, a direct, concrete injury to his business or property, he has not met RICO’s statutory-standing requirement.

This conclusion is well-supported by the reasoning in the Sixth Circuit’s recent en banc decision, which stressed that there must be meaningful limits to what constitutes an injury to business or property under RICO. *See Jackson*, 731 F.3d at 562–63. It is also bolstered by other Sixth Circuit precedent requiring that the RICO injury be one that occurred directly to the plaintiff. *See Perry v. Am. Tobacco Co.*, 324 F.3d 845, 849 (6th Cir. 2003) (observing that statutory standing to bring a RICO claim is “always limited to parties who are directly injured”). Finally, its conclusion falls squarely in line with those reached by other courts. In *Steele v. Hospital Corporation of America*, 36 F.3d 69 (9th Cir. 1994), the Ninth Circuit addressed a RICO claim involving an alleged conspiracy to overbill insurance companies. In finding that the plaintiffs, four former patients, lacked statutory standing under RICO, the Ninth Circuit reasoned as follows:

It is not enough that the patients show that their insurance company had to pay out more than it otherwise would have without the alleged RICO violation. This does not constitute financial loss to them. . . . [I]n this case, if the patients have paid none of the allegedly excessive charges out of their own pockets because those charges were covered by insurance, then they have suffered no financial loss.

The patients argue that they have suffered financial loss because the excessive charges depleted their insurance benefits. Read, father of one of the adolescent patients, stated in his deposition, “I could have used some of those [insurance] benefits for myself.” However, he does not specify an instance where he had to pay a claim out of his own funds because his insurance had been exhausted. He has not described a concrete financial loss, but rather a speculative injury, contingent on actually seeking medical care for himself. [These] speculative injuries do not serve to confer standing under RICO, unless they become concrete and actual.

Id. at 70–71; *see also Maio v. Aetna, Inc.*, 221 F.3d 472, 483 (3d Cir. 2000) (reaffirming that to establish statutory standing, a RICO plaintiff must allege a “concrete financial loss”). The Court agrees with this reasoning, and finds that Plaintiff’s pointing to a loss purportedly incurred by his

insurance company falls short of RICO's statutory-standing requirement that he plead a "concrete and actual" loss to *his* business or property. *See Steele*, 36 F.3d at 71.

Plaintiff Short also makes an argument that he became subrogated to his insurer when his insurer paid for the Risperdal on his behalf. He alleges that in Michigan, a subrogated injured party may seek recovery of amounts paid by his insurer as a component of damages in a suit. But this is not how subrogation works. In fact, it is well established that when an insurance company pays an insured's expense for a prescription drug or other covered good or service, the insurer is the only real party in interest. *See, e.g., Sinai Hosp. of Detroit v. Sivak*, 276 N.W.2d 518, 520 (Mich. Ct. App. 1979) ("The subrogee is generally recognized as the real party in interest. Generally, an insured, who no longer has any interest in the recovery, cannot sue.") Therefore, this argument does not disturb the Court's conclusion that Plaintiff Short lacks statutory standing to pursue his RICO claim. Accordingly, the Court **GRANTS** the Motion to Dismiss as to the federal RICO claim.

B. Plaintiff's State Law Claims

Plaintiff also brings claims against Defendants under the laws of the State of Michigan. As noted above, the Court has diversity jurisdiction of Plaintiff's state law claims on the grounds that Plaintiff is a resident of the State of Michigan and Defendants' principal place of business is New Jersey, and the amount in controversy exceeds the appropriate threshold. *See* 28 U.S.C. § 1332.

1. Plaintiff's Michigan Consumer Protection Act Claims

The Michigan Consumer Protections Act protects Michigan consumers from "unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce." Mich. Comp. Laws § 445.903(1). However, the MCPA does not apply to "[a] transaction or conduct

specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States.” *Id.* § 445.904(1)(a).

Defendants argue that dismissal is appropriate because the MCPA does not apply to activities regulated by the federal Food & Drug Administration. (R. 11, Def. Br. at 14–15, PageID # 176–77.) Plaintiff argues that the Food & Drug Administration did not approve the marketing of Risperdal to adolescents; rather, it refused this request, and so the Michigan Consumer Protections Act applies. (R. 16, Pl. Resp. Br. at 17, PageID # 265.) The viability of Plaintiff’s claim, therefore, depends on whether express approval or authorization is necessary to exempt a claim from the scope of the MCPA.

“The Michigan Supreme Court has held that, in determining if a transaction or conduct is exempt from the scope of the MCPA, ‘the relevant inquiry is not whether the specific misconduct alleged by the plaintiffs is ‘specifically authorized.’ Rather, it is whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited.’”

Peter v. Stryker Orthopaedics, Inc., 581 F. Supp. 2d 813, 816 (E.D. Mich. 2008) (quoting *Smith v. Globe Life Ins. Co.*, 597 N.W.2d 28, 38 (Mich. 1999)). In an effort to distinguish this controlling case law, Plaintiff admits that it is “persuasive” and points to the MCPA’s statutory language, without citing any authority that supports its interpretation. (R. 16, Pl. Resp. Br. at 18, PageID # 266.) Plaintiff’s argument simply lacks a foundation in case law. Accordingly, the Court **GRANTS** the motion to dismiss as to the MCPA claim.

2. Plaintiff’s Michigan Products Liability Act Claims

The Michigan Products Liability Act creates broad immunity for pharmaceutical manufacturers. With two limited exceptions, the statute provides that “a product that is a drug is not

defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration approval at the time the drug left the control of the manufacturer or seller.” Mich. Comp. Laws § 600.2946. This liability protection does not apply if the defendant:

- (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted [to the FDA] . . . and the drug would not have been approved or the [FDA] would have withdrawn approval if the information were accurately submitted, [or]
- (b) Makes an illegal payment to an official or employee of the [FDA] for the purpose of securing or maintaining approval of the drug.

Id. § 600.2946. The intentional-misrepresentation exception is at issue here.

“Federal law preempts and limits these statutory exceptions.” *Blair v. Genentech, Inc.*, No. 1:11-CV-482, 2011 WL 5088969, at *5 (W.D. Mich. Oct. 26, 2011) (citing *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 965–66 (6th Cir. 2004) (citing *Buckman Co. v. Pl's Legal Comm.*, 531 U.S. 341, 350 (2001))). In *Buckman*, the Supreme Court determined that “[s]tate law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Agency’s judgment and objectives.” 531 U.S. at 350. In *Garcia*, the Sixth Circuit found that the same analysis applies to the exceptions in the Michigan statute. See 384 F.3d at 966 (“*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.”). Accordingly, Defendants argue that the Michigan Products Liability Act does not apply to products such as Risperdal that were at all times approved by the Food & Drug Administration. (R. 11, Def. Br. at 16–17, PageID # 178–79.)

Defendants also argue that Plaintiff's claim does not fall into either of the statute's two exceptions. (R. 11, Def. Br. at 17–22, PageID # 179–84.) Plaintiff counters that Michigan's Products Liability Act is "nuanced" and applies only if the drug is "promoted and marketed within the scope" of the Food & Drug Administration's approval. (R. 16, Pl. Resp. Br. at 19–24, PageID # 267–72.) Defendants assert that the Michigan Products Liability Act has no "overpromotion" exception. (R. 20, Def. Rep. Br. at 13, PageID # 304.)

Again, based on controlling case law, the claim must be dismissed. The Sixth Circuit has observed that "Michigan law generally immunizes a drug manufacturer from liability for FDA-approved drugs *unless the manufacturer intentionally withholds or misrepresents information that would have led the FDA to deny approval or withdraw the drug.*" *In re Aredia & Zometa Products Liab. Litig.*, 352 F. App'x 994, 995 (6th Cir. 2009) (*citing* Mich. Comp. Laws. § 600.2946(5)(a)) (emphasis added). There is no allegation in this case that any information relating to off-label usage would have affected the on-label usage that the FDA approved, and so the immunity applies.

Moreover, Defendants correctly note that courts have repeatedly rejected Plaintiff's position, and that companies such as defendants are entitled to the immunity if the drug at issue has FDA approval, regardless of whether the defendant has improperly promoted the off-label use of a drug. (R. 20, Def. Rep. Br. at 12–13, PageID # 303–04.) Indeed, the "Michigan Supreme Court has stated that this statute provides 'an absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller.'" *Griffus v. Novartis Pharm. Corp.*, No. 06-10891, 2006 WL 2583129, at *1 (E.D. Mich. Sept. 6, 2006) (quoting *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003)).

In *Griffus*, the district court found that a plaintiff's argument that she used the drug for a non-approved purpose "unpersuasive" because drugs are sometimes used for purposes besides those for which the FDA approved them. *See id.* Accordingly, the "absolute defense" applies, and the Court **GRANTS** the motion to dismiss.

IV. CONCLUSION

For the reasons detailed above, the Defendants' motion to dismiss for failure to state a claim (docket no. 10) is **GRANTED**.

IT IS SO ORDERED.

Dated: May 11, 2015

/s/ Robert J. Jonker
ROBERT J. JONKER
UNITED STATES DISTRICT JUDGE